

Serial No. 10/724,474**Patent
13010-02USA****REMARKS**

Claims 1-2, 5-13, and 15-21 are pending in the application.

Rejection Under 35 U.S.C. § 102(b) Over Joslin (U.S. Patent No. 4,353,868)

Claims 1, 2, 5-9, 12, 13 and 19-21 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Joslin '868. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants assert that the presently claimed invention is distinguished from Joslin '868.

Presently claimed invention

The present invention is directed to a device for sample collection and storage. The samples, liquid or solid, collected by the inventive device may be stored for long periods of time with minimal degradation so that the biological material is substantially intact to be analyzed.

Joslin '868

Joslin '868 discloses a specimen collecting device including a swab and a reservoir containing a quantity of a liquid specimen preserving or sustaining medium. The specimen carrying swab is continuously held in contact with the pad and the swab tip will remain wet or soaked by the medium. The liquid culture-sustaining medium usable in the device is chosen on the basis of the particular type of culture to be preserved. The liquid culture medium used may be Stuart's modified media, or a liquid culture of bile, blood or egg. However, Joslin '868 fails to disclose or suggest a pad comprising chemical preservatives or enzyme inhibitors, as in the presently claimed invention.

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13010-02USA****Distinctions of the present invention over Joslin '868.**

The chemical preservative or enzyme inhibitor disclosed in the presently claimed invention is used as an inhibitor of microbiological growth and degradative enzymes such as proteases. Therefore, these preservatives or enzyme inhibitors are necessary for long-term storage of the samples collected by the inventive device. The preservative or enzyme inhibitor disclosed in the presently claimed invention includes among others, DNase inhibitors, EDTA, buffers, sodium azide, sodium benzoate, procline, and thimerosal.

Contrary to the presently claimed invention, Joslin '868 discloses use of liquid culture-sustaining medium to promote the growth of culture or microorganisms, rather than inhibiting microbiological growth. Accordingly, Joslin '868 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. § 102(b) Over McClintock (U.S. Patent No. 5,980,828)

Claims 1, 2, 5, 8 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by McClintock '828. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants assert that the presently claimed invention is distinguished from McClintock '828.

McClintock '828

McClintock '828 discloses a flat plate-like assay device to detect chemiluminescence. Further, the device is used to measure adenosine triphosphate (ATP) to indirectly measure the bacterial content by collecting the suspected sample with the collection pad and moving the sample to the reading portion containing chemiluminescent reagents by folding the collecting arm comprising the collection pad to touch the reading portion. However, McClintock '828

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fails to disclose or suggest a device for collecting and storing biological samples comprising a pad comprising chemical preservatives or enzyme inhibitors, as in the presently claimed invention.

Distinctions of the present invention over McClintock '828

Chemiluminescent reagents disclosed in McClintock '828 are irrelevant to the preservatives or enzyme inhibitors disclosed in the presently claimed invention. The chemiluminescent reagents in McClintock '828 are used for chemiluminescent reaction to detect ATP and indirectly measure bacterial content. Accordingly, McClintock '828 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. § 103(a) Over Dechow '068 in view of Bull (U.S. Patent No. 5,275,953)

Claim 8 has been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow '068 in view of Bull '953. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow '068 discloses a device for collecting samples. However, Dechow '068 fails to disclose a pad comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Bull '953 is cited for the disclosure of a chemical preservative or enzyme inhibitor. However, Bull '953 discloses a coating agent, which inhibits the activation of blood elements responsible for initiating blood clotting processes, and Bull '953 also fails to disclose or suggest a pad comprising chemical preservatives or enzyme inhibition. Therefore, Bull '953 fails to remedy the deficiencies in the Dechow '068 reference. Accordingly, the presently claimed invention is not obvious over the cited references and it is believed that the rejection has been overcome.

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13010-02USA****Rejection Under 35 U.S.C. § 103(a) Over Dechow '068 in view of Bull '953 and Bazell****(U.S. Patent No. 4,370,987)**

Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow '068 in view of Bazell '987. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow '068 and Bull '953 are discussed above. Dechow '068 and Bull '953 fail to disclose a pad comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Bazell '987 is cited by the Examiner for its disclosure of a syringe having a unidirectional piston. However, Bazell '987 also fails to disclose or suggest a pad comprising chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the Dechow '068 and Bull '953 references. Accordingly, the presently claimed invention is not obvious over the cited references and the rejection has been overcome.

Rejection Under 35 U.S.C. § 103(a) Over Dechow '068 in view of Bull '953 and Erickson**(U.S. Patent No. 6,602,205)**

Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow '068 in view of Bull '953. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow '068 and Bull '953 are discussed above. Dechow '068 and Bull '953 fail to disclose a pad comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Erickson '205 is cited by the Examiner for its disclosure of a capillary tubing. However, Erickson '205 also fails to disclose or suggest a pad comprising chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the

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Dechow '068 and Bull '953 references. Accordingly, the presently claimed invention is not obvious over the cited references and the rejection has been overcome.

Rejection Under 35 U.S.C. § 103(a) Over Joslin '868 in view of Sak (U.S. Patent Application Publication No. 2002/0161313)

Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over Joslin '868 in view of Sak '313. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection is respectfully requested.

Joslin '868 is discussed above. Joslin '868 fails to disclose a pad comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Sak '313 is cited by the Examiner for its disclosure of written instructions on using a device for collecting biological samples. However, Sak '313 also fails to disclose or suggest a pad comprising chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the Joslin '868 reference. Accordingly, the presently claimed invention is not obvious over the cited references and the rejection has been overcome.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. 502486.

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Respectfully submitted,

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